UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

UNITED STATES OF AMERICA,

Plaintiff,

Case No. 18-cr-145-pp

v.

LISA HOFSCHULZ,
and ROBERT HOFSCHULZ,

Defendants.

PRELIMINARY RULING ON DISPUTED PROPOSED JURY INSTRUCTIONS (DKT. NO. 115 at 20-39)

This case is scheduled for a jury trial starting August 2, 2021. Dkt. No. 151. The parties have submitted proposed jury instructions. Dkt. No. 115 at pp. 20-39. Normally the court would wait to rule on disputed jury instructions until after presentation of the evidence; depending on what evidence is admitted at trial, some proposed instructions become unnecessary and others must be modified. Here, the government has asked the court to rule on the disputed instructions sooner.

This order provides the parties with the court's preliminary ruling on specific, disputed instructions. The court emphasizes the preliminary nature of this ruling; as it explains later in the decision, if certain evidence comes in at trial, the court may be required to modify the conclusions it reaches here.

A. Background

On June 26, 2018, the grand jury issued an indictment charging Lisa and Robert Hofshulz with knowingly and intentionally conspiring with each other and others to distribute controlled substances outside of a professional medical practice and not for a legitimate medical purpose in violation of 21 U.S.C. §§841(a)(1), 841(b)(1)(C) and 846. Dkt. No. 1 at 1-5. The indictment alleged that Lisa Hofschulz, an advanced nurse practitioner, had owned and operated a medical clinic called Clinical Pain Consultants since December 2014; that she was registered with the DEA and authorized to prescribe oxycodone, morphine, fentanyl, methadone, lorazepam and Adderall. Id. at 1-2. It alleged that Robert Hofshulz was not such a registered prescriber, id. at 2, but that he did become CPC's registered agent in December 2014, id. at 3. The grand jury charged that Lisa Hofschulz prescribed "excessive dosages of controlled substances outside of a professional medical practice and not for a legitimate medical purpose especially oxycodone and methadone." Id. at 4. It alleged that Lisa and Robert Hofschulz hired other prescribers to prescribe in the same way as Lisa Hofschulz, and directed a person not authorized to issue prescriptions to distribute them when authorized prescribers refused to do so. Id. at 4.

The indictment also included thirteen counts of knowingly and intentionally distributing and dispensing unlawfully certain controlled substances to certain patients on certain dates, outside of a professional medical practice and not for a legitimate medical purpose; all thirteen counts

named Lisa Hofschulz as a defendant and four also named Robert Hofschulz. Id. at 6-7.

Eight months later, on February 26, 2019, the grand jury returned a superseding indictment. Dkt. No. 29. The superseding indictment added a fifteenth count, alleged solely against Lisa Hofschulz:

> 1. On or about November 19, 2015, in the State and Eastern District of Wisconsin,
>
> **LISA HOFSCHULZ**,
>
> Knowingly and intentionally distributed Oxycodone and Morphine, both Schedule II controlled substances, to F.E. outside of a professional medical practice and not for a legitimate medical purpose.
>
> 2. The death of F.E. resulted from the use of the Oxycodone and Morphine distributed by Lisa Hofschulz.
>
> All in violation of Title 21, United States Code, Sections 841(a)(1) and (b)(1)(C), and Title 18, United States Code, Section 2.

Id. at 8.

B. The Parties' Proposed Instructions

While the government has proposed many of the Seventh Circuit's pattern criminal jury instructions and several "special"—that is, non-pattern—instructions, the defendants have proposed their own versions of only a few instructions and the parties do not dispute some of those. This preliminary ruling addresses only those instructions the parties have indicated they dispute.

1. *Elements of 21 U.S.C. § 841(a)(1)*

The government has proposed the following instruction:

Controlled Substances – Illegal Distribution

To sustain the charge of distributing or dispensing unlawfully a controlled substance, as charged in all counts of the indictment, the United States must prove the following propositions:

First, that the defendant knowingly distributed or dispensed a controlled substance(s) or attempted to do so;

Second, that the defendant did so by prescribing the controlled substance(s) outside of the usual course of professional medical practice and not for a legitimate medical purpose; and

Third, that the defendant knew that the substance was some kind of a controlled substance.

If you find from your consideration of all the evidence that each of these propositions has been proved beyond a reasonable doubt, then you should find the defendant guilty. If, on the other hand, you find from your consideration of all the evidence that any one of these propositions has not been proved beyond a reasonable doubt, then you should find the defendant not guilty.

Dkt. No. 115 at 23.

Defendant Robert Hofshulz has proposed no alternative to this instruction.

Defendant Lisa Hofschulz has proposed the following alternative:

Controlled Substances – Illegal Distribution

To sustain the charge of distributing or dispensing unlawfully a controlled substance, as charged in each count of the indictment, the government just prove the following propositions:

First, that the defendant knowingly distributed or dispensed a controlled substance(s);

Second, that the defendant knew that the substance was some kind of controlled substance;

> Third, that the defendant distributed or dispensed the controlled substance(s) outside the usual course of professional practice and not for a legitimate medical purpose; and
>
> Fourth, that the defendant did so knowingly and intentionally.
>
> If you find from your consideration of all the evidence that each of these propositions has been proved beyond a reasonable doubt, then you should find the defendant guilty. If, on the other hand, you find from your consideration of all the evidence that any one of these propositions has not been proved beyond a reasonable doubt, then you should find the defendant not guilty.

Dkt. No. 115 at 32.

2. *Definition of Knowingly*

Among the Seventh Circuit pattern instructions the government has proposed is Pattern Instruction 4.10. Dkt. No. 115 at 20. That instruction reads:

4.10 DEFINITION OF KNOWINGLY

> A person acts "knowingly" if he realizes what he is doing and is aware of the nature of his conduct, and does not act through ignorance, mistake, or accident. [In deciding whether the defendant acted knowingly, you may consider all of the evidence, including what the defendant did or said.]
>
> [You may find that the defendant acted knowingly if you find beyond a reasonable doubt that he believed it was highly probable that [state fact as to which knowledge is in question, *e.g.*, "drugs were in the suitcase," "the financial transaction was false,"] and that he took deliberate action to avoid learning that fact. You may not find that the defendant acted knowingly if he was merely mistaken or careless in not discovering the truth, or if he failed to make an effort to discovery the truth.]

The William J. Bauer Pattern Criminal Jury Instructions of the Seventh Circuit (2020 Ed.), Instruction 4.10.

Defendant Robert Hofschulz has not proposed an alternative to the pattern instruction.

Defendant Lisa Hofschulz proposes the following alternative:

> **Definition of Knowingly**
>
> A person acts knowingly if she realizes what he [sic] is doing and is aware of the nature of her conduct, and does not act through ignorance, mistake, or accident. In the context of this case, this means that the government must prove beyond a reasonable doubt that Lisa Hofschulz knew that her prescribing of the controlled substance at issue was both outside the usual course of medical practice and not for a legitimate medical purpose.

Dkt. No. 115 at 34.

3. *Instructions Related to Illegal Prescription of Controlled Substances*

The government has proposed the following instructions:

> **Outside the Usual Course of Professional Medical Practice and Not for a Legitimate Purpose**
>
> Federal law authorizes registered medical practitioners to dispense a controlled substance by issuing a lawful prescription. Registered practitioners are exempt from criminal liability if they distribute or dispense controlled substances for a legitimate medical purpose while acting in the usual course of professional practice. A registered practitioner violates Section 841(a)(1) of Title 21 of the United States Code if the practitioner distributes or dispenses a controlled substance without a legitimate medical purpose and outside the usual course of standard professional practice.
>
> A prescriber's own treatment methods do not themselves establish what constitutes professional medical practice. In determining whether the defendant's conduct was outside the usual course of professional medical practice, you should consider the testimony you have heard relating to what has been characterized during the trial as the norms of professional practice. You should consider the defendant's actions as a whole, the circumstances surrounding them, and the extent of severity of any violations of professional norms you find the defendant may have committed.

Dkt. No. 115 at 24.

Good Faith in the Usual Course of Professional Medical Practice

> The Defendant may not be convicted if she dispenses or causes to be dispensed controlled substances in good faith in accordance with the standards of professional medical practice generally recognized and accepted in the United States. Only the lawful acts of a prescriber, however, are exempted from prosecution under the law. Good faith in this context means an observance of conduct in accordance with what the prescriber should reasonably believe to be proper medical practice defined by generally recognized and accepted standards of professional medical practice. In determining whether the defendant acted in good faith in the usual course of professional medical practice, you may consider all of the evidence in the case which relates to that conduct.

Dkt. No. 115 at 25.

Defendant Robert Hofschulz does not appear to object to these two instructions. Dkt. No. 115 at 29 ("In addition to those instructions sought by the Government, Robert Hofschulz seeks the Court to give . . . ."). He asks, however, that the court give an additional good faith instruction as to him. He asks the court to give Seventh Circuit Pattern Jury Instruction 6.11:

6.11 GOOD FAITH—TAX AND OTHER TECHNICAL STATUTE CASES

> A person does not act willfully if he believes in good faith that he is acting within the law, or that his actions comply with the law. Therefore, if the defendant actually believed that what he was doing was in accord with the [tax; currency structuring; other technical statute] laws, then he did not willfully [evade taxes; fail to file tax returns; make a false statement on a tax return; other charged offense]. This is so even if the defendant's belief was not objectively reasonable, as long as he held the belief in good faith. However, you may consider the reasonableness of the defendant's belief, together with all the other evidence in the case, in determining whether the defendant held that belief in good faith.

The William J. Bauer Pattern Criminal Jury Instructions of the Seventh Circuit (2020 Ed.), Instruction 6.11.

Defendant Lisa Hofschulz proposes an alternative instruction to those proposed by the government:

Good Faith in the Usual Course of Professional Medical Practice

A licensed practitioner such as Lisa Hofschulz is authorized to prescribe drugs only when she is acting as a medical practitioner. In making a medical judgment concerning the right treatment for an individual patient, medical practitioners have discretion to choose among a wide range of available options. Therefore, in determining whether Lisa Hofschulz acted knowingly without a legitimate medical purpose, you should examine all of her actions and the totality of the circumstances surrounding those actions.

Lisa Hofschulz contends that she prescribed controlled substances in good faith. The offenses charged in the indictment require proof that Lisa Hofschulz knowingly and intentionally distributed controlled substances outside the usual course of professional practice and not for a legitimate medical purpose. If you find that Lisa Hofschulz acted in good faith, that would be a complete defense for these charges because good faith on the part of Lisa Hofschulz would be inconsistent with her acting knowingly and intentionally. A person acts in good faith when he or she has an honestly held belief of the truth of the statements being given to them even though the belief turns out to be inaccurate or incorrect. God faith in this context means good intentions and the honest exercise of professional judgment as to a patient's medical needs.

Lisa Hofschulz does not have the burden of proving good faith. Good faith is a defense because it is inconsistent with the requirement of the offenses that she acted knowingly and intentionally. As I have instructed you, the government must prove Lisa Hofschulz's mental state beyond a reasonable doubt. In deciding whether the Government proved that Lisa Hofschulz acted knowingly and intentionally, or instead whether Lisa Hofschulz acted in good faith, you should consider all the evidence presented in the case that may bear on Lisa Hofschulz's state of mind.

If you find from the evidence that the government failed to prove beyond a reasonable doubt that Lisa Hofschulz acted knowingly or intentionally, or that the government failed to prove any other element as to any one of the counts, you must find Lisa Hofschulz not guilty as to that count. If, on the other hand, you find that the government proved beyond a reasonable doubt each of the

elements as to any count, then you should find Lisa Hofschulz guilty as to that count.

Dkt. No. 115 at 35.

4. *Standard of Care Instruction*

Lisa Hofschulz has proposed the following instruction:

Not Malpractice

In your experiences, some of you may be familiar with or have heard of medical malpractice or the standard of care. This is not a medical malpractice case. Those terms are used in civil cases when a patient is seeking damages. Medical malpractice is the unwarranted departure from generally accepted standards of medical practice allegedly resulting in injury to a patient. This, however, is a criminal case, and you must apply the instructions I am giving to you now and determine whether Lisa Hofschulz distributed or dispensed a controlled substance outside the usual course of professional practice and not for a legitimate medical purples. You are not deciding whether Lisa Hofschulz should be liable for medical malpractice.

Dkt. No. 115 at 39.

The government objects to this instruction. Id.

C. Analysis

1. *Governing Law*

The indictment alleges that the defendants conspired to violate, or violated, 21 U.S.C. §841(a)(1). That statute states:

(a) Unlawful Acts

Except as authorized by this subchapter, it shall be unlawful for any person knowingly or intentionally—

(1) to manufacture, distribute, or dispense, or possess with intent to manufacture, distribute, or dispense, a controlled substance . . . .

Most commonly, the government brings charges for violations of §841(a)(1) against defendants who have no legal authority to distribute or dispense controlled substances. The Seventh Circuit has two pattern instructions for cases alleging violations of 21 U.S.C. §841(a)(1), both of which were intended for that circumstance—a case in which the defendant had no legal authority to distribute or dispense controlled substances. The first—an instruction on the elements of distribution of a controlled substance—requires the government to prove beyond a reasonable doubt that the defendant knowingly distributed a particular controlled substance and that she knew the substance was some kind of controlled substance. The William J. Bauer Pattern Criminal Jury Instructions of the Seventh Circuit (2020 Ed.), p. 880. The second—an instruction on the elements of possession with intent to distribute—requires the government to prove beyond a reasonable doubt that the defendant knowingly possessed a particular controlled substance, that she intended to distribute that person to another person and that she knew it was some kind of controlled substance. Id., p. 883.

Neither of these instructions fits the circumstances of this case, in which the defendant accused of having violated the statute is a registered prescriber authorized to possess and distribute controlled substances knowing that they are controlled substances. A person registered and authorized to prescribe controlled substances would not violate the statute simply because she possessed a controlled substance, intended to distribute it to another person and knew it was a controlled substance; while those elements describe a *crime*

for someone who is not a licensed prescriber, they describe the *job* of someone who is a licensed prescriber.

In December 1975, the Supreme Court decided United States v. Moore, 423 U.S. 122 (1975). A doctor had been charged with, tried for and convicted of violating 21 U.S.C. §841(a)(1) by unlawfully distributing and dispensing methadone. Id. at 124-25. The D.C. Court of Appeals, while assuming that the defendant had acted wrongfully (the defendant admitted that he had not observed "generally accepted medical practices," had run a large-scale operation writing hundreds of methadone prescriptions a day to patients who received only "the most perfunctory" examinations before being prescribed the amount of the drug they requested, id. at 126-27), held that the doctor could not be prosecuted under §841 and that Congress had intended for registered physicians to be prosecuted only under 21 U.S.C. §§842 and 843. Id. at 127-28.

The Supreme Court disagreed. It concluded that in enacting §841, "Congress was concerned with the nature of the drug transaction, rather than with the status of the defendant." Id. at 134. In noting that the House Committee Report on what became the Controlled Substances Act stated that the bill "makes transactions outside the legitimate distribution chain illegal," the Court stated that the "most sensible interpretation" of that language was that a violation "was intended to turn on whether the 'transaction' falls within or without legitimate channels." Id. at 135.

In response to the defendant's argument that the specific conduct prohibited by §841 is authorized for a registered prescriber, the Supreme Court noted that '[t]he trial judge assumed that a physician's activities are authorized only if they are within the usual course of professional practice." Id. at 138. The trial judge had told the jury that to convict the defendant, it must find

> beyond a reasonable doubt that a physician, who knowingly or intentionally, did dispense or distribute methadone) by prescription, did so other than in good faith for detoxification in the usual course of a professional practice and in accordance with a standard of medical practice generally recognized and accepted in the United States.

Id. at 138-39. The Court recounted that the court of appeals had not addressed the defendant's argument because it had concluded that doctors could not be prosecuted under §841, but that it had suggested that if a doctor *could* be prosecuted under that section, "he could not be prosecuted merely because his activities fall outside the 'usual course of practice.'" Id. at 139.

Again, the Supreme Court disagreed. It cited various provisions of the Controlled Substances Act that "reflect the intent of Congress to confine authorized medical practice within accepted limits." Id. at 141-42. In particular, the Court referenced §802(2), which defined a "practitioner" as someone who dispensed drugs "in the course of professional practice or research." Id. at 141. The Moore Court concluded that there was sufficient evidence presented at trial "for the jury to find that respondent's conduct exceeded the bounds of 'professional practice.'" Id. at 142. The Court said,

> As detailed above, he gave inadequate physical examinations or none at all. He ignored the results of the tests he did make. He did not give methadone at the clinic and took no precautions against its

> misuse and diversion. He did not regulate the dosage at all, prescribing as much and as frequently as the patient demanded. He did not charge for medical services rendered, but graduated his fee according to the number of tablets desired. In practical effect, he acted as a large-scale "pusher" not as a physician.

Id. at 142-43.

Ten months before the Supreme Court issued its decision in Moore, the Seventh Circuit had faced the same issue. In United States v. Green, 511 F.2d 1062 (7th Cir. 1975), the defendants (physicians and a pharmacist) had been convicted of illegally "dispensing or distributing of controlled substances pursuant to prescriptions allegedly issued without a legitimate medical purpose or outside the usual course of professional practice" in violation of §841(a) and 21 C.F.R. §306.04(a)[1]. Green, 511 F.2d at 1063. The defendants challenged their convictions based on the D.C. Court of Appeals' decision in Moore—the one the Supreme Court later would overturn. Id. at 1067-68. As the Supreme Court would do ten months later, the Seventh Circuit concluded that §841 "does not exclude physicians from its coverage." Id. at 1069. The court then considered "precisely what type of dispensing or distributing is authorized by the exception clause of section 841." Id. The court looked to 21 C.F.R. §306.04(a), which "provide[d] that a prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by a practitioner acting in the usual course of his professional practice." Id. The court concluded that the regulation did not expand the criminal statute, and that the defendants had violated the statute because "there were wholesale sales of

[1] Now 21 C.F.R. §1306.04.

prescriptions without even the pretense of a legitimate medical purpose or standard medical procedures." Id. at 1070.

One of the Green defendants challenged the jury instruction "on what constituted a defense by a physician to an action under section 841(a)." Id. at 1071. The judge had instructed the jury that it was a defense "if the substance is prescribed by [the physician] in good faith in medically treating a patient." Id.[2] The defendant argued that the court should have given "an instruction that would have established a defense on the mere showing that a controlled substance was prescribed by a physician for his patient's own use." Id. The Seventh Circuit rejected this argument, finding that the proffered instruction was "too broad" and would have had the effect of applying the rationale used by the court of appeals in Moore. Id. The court stated,

> We have decided that a prescription issued by a physician that is so far removed from a physician's professional responsibilities (i.e.

[2] The entire instruction given by the trial judge read: "Federal law authorizes a licensed physician to prescribe controlled substances of the kinds charged in the indictment, if the drug is prescribed in the course of the physician's professional practice. The defendant [] is a licensed physician. It is therefore a defense to the charges in this indictment that the controlled substances were prescribed by him in the course of his professional practice. A controlled substance is prescribed by a physician in the course of his professional practice, and therefore lawfully, if the substance is prescribed by him in good faith in medically treating a patient. In order to determine whether or not a prescription or prescriptions were issued in the course of a defendant physician's professional practice, you may consider all of the evidence of circumstances surrounding the prescribing of the substance in question, the statements of the parties to the prescription transaction, any expert testimony as to what is the usual course of medical practice, and any other competent evidence bearing on the purpose for which the substances in question were prescribed. Unless you find beyond a reasonable doubt that an act of prescribing charged in the indictment against a physician defendant was not done by the defendant physician in the course of his professional practice,, then you should not find him guilty." Green, 511 F.2d at 1071 n.22.

> more than mere technical violations of his authorization) violates section 841(a). The 'good faith medical treatment' instruction seems to be an accurate reflection of this holding and in no way was prejudicial to the defendant's case.

Id.

The current iteration of the regulation referenced in Green is 21 C.F.R. §1306.04(a)—which states:

> **§1306.04 Purpose of issue of prescription.**
>
> (a) A prescription for a controlled substance to be effective must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice. The responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription. An order purporting to be a prescription issued not in the usual course of professional treatment or in legitimate and authorized research is not a prescription within the meaning and intent of section 309 of the Act (21 U.S.C. 829) and the person knowingly filling such a purported prescription, as well as the person issuing it, shall be subject to the penalties provided for violations of the provisions of law relating to controlled substances.

Later in 2007—after the Supreme Court had issued its decision in Moore—the Seventh Circuit decided United States v. Bek, 493 F.3d 790 (7th Cir. 2007). The defendant doctor in Bek ran a pain-management clinic in Indiana; the jury convicted him of, among other things, illegally prescribing controlled substances. Id. at 795. On appeal, the defendant argued that the evidence was insufficient to support his convictions for "unauthorized distribution of controlled substances because the government's experts testified as to the civil 'standard of care' rather than the higher criminal 'course of professional practice' standard." Id. at 798. As the Seventh Circuit put it,

"[e]ssentially, Bek argues that the government's evidence proved malpractice, not criminal conduct." Id.

Citing the Supreme Court's decision in Moore and its own decision in Green, the Seventh Circuit said that to convict a registered practitioner of violating §841(a), "the government must show that he prescribed controlled substances outside 'the course of professional practice.'" Id. The court found that the defendant's concerns about the jury being misled were "allayed by the jury instructions, which he did not contest." Id.

> The instructions stated that the government had to prove that Bek distributed controlled substances "other than for a legitimate medical purpose or not within the bounds of professional medical or pharmaceutical practice." The court also specifically instructed the jury that "[i]n determining whether the defendant's conduct was within the bounds of professional medical practice, you should consider the testimony you have heard relating to what has been characterized during trial as the 'norms' of professional practice." We must presume that the jury followed these proper instructions, *see Laxton v. Bartow*, 421 F.3d 565, 573 (7th Cir. 2005), and relied upon the evidence of the norms of professional practice to determine whether Bek's conduct fell outside the "course of professional practice."

Id. at 798-99.

The court went on to conclude that the evidence presented at trial satisfied "the criminal standard":

> Witnesses described practices inconsistent with legitimate medical care: uniform, superficial, and careless medical examinations (e.g., blood pressures taken through clothing); exceedingly poor record-keeping, which one expert called "astonishing" (e.g., reporting temperatures of 98.6° for nearly every patient); and a disregard of blatant signs of drug abuse. The experts testified that Bek prescribed the "same menu" and same dosages of drugs to different patients, regardless of body build and kidney function. Further, they noted that contrary to accepted medical practice, Bek prescribed multiple medications having the same effects (e.g., two muscle

> relaxants prescribed at a time), and drugs that are dangerous when taken in combination. And, they concluded that Bek's conduct "was for other than legitimate medical purpose." The jury had more than enough evidence to determine that Bek had a general practice of prescribing controlled substances outside the course of professional conduct.

Id. at 799.

The following year, the Seventh Circuit decided United States v. Chube II, 538 F.3d 693 (7th Cir. 2008). The defendants, medical doctor siblings, were convicted of unlawful distribution of controlled substances. Id. at 694-95. On appeal, the defendants argued that "their convictions . . . assess their actions by reference to the standard of care applicable in a civil malpractice suit, but the proper standard is the one found in the Controlled Substances Act ("CSA"), which authorizes the conviction of a registered practitioner only if the prescription was written without a legitimate medical purpose and outside the scope of professional practice." Id. at 695. The defendants alleged that the testimony of the government's expert witnesses "conflated the civil and criminal standards of care and thus created a risk that the jury found liability not because it concluded that the Doctors' acts of prescribing medication fell outside the scope of legitimate medical practice, but instead because it thought they had been careless." Id. at 696. The "battleground of the litigation . . . was whether the Doctors knew that no legitimate medical reason existed for prescribing painkillers to" the patients who had testified. Id.

The defendants had filed a pretrial motion *in limine*, arguing that the court should have excluded some or all the testimony of two government experts. Id. at 697.

> Dr. [Theodore] Parran, who specialize[d] in internal medicine and addiction medicine, evaluated all 98 patient files in the record. Based on that review, he concluded that the prescribing "was not done consistent with the usual standards of medical practice" and thus was not done with a "legitimate medical purpose." Dr. [Robert] Barkin was called as an expert on pharmacology. Though not a medical doctor, Dr. Barkin received his doctorate in clinical pharmacy in 1984 and is board-certified by various associates for pain management and forensic medicine. Like Dr. Parran, Dr. Barkin testified solely on the basis of the patient charts, although he reviewed only a selection. He, too, concluded that the prescriptions in the carts that he reviewed were issued "[o]utside the scope of medical practice, not for legitimate purposes."

Id. at 696-97.

The defendants described the purpose of their motion *in limine* as a "request that [the trial court] enter a preliminary ruling prohibiting the Government from introducing any evidence at trial that the Chubes' treatment of patients did not conform to the 'standards of medical practice', or any other evidence that would be suggestive of a violation of the civil standard of care applicable in medical malpractice cases." Id. at 697. The government characterized the purpose of the motion as an attempt to exclude all expert testimony "that would suggest a violation of the standard of care applicable in civil medical malpractice cases." Id. The government conceded that "the expert testimony would not be conclusive on the question of the Doctors' criminal liability," but argued that the evidence was relevant "to circumstantially establishing that the defendants had knowingly and intentionally distributed drugs as mere pill-pushers rather than in course of a professional medical practice." Id. The defendants replied that they agreed the testimony had some relevance; they were trying only to limit any portion of the evidence that

"tended to conflate the civil and criminal standards, not to exclude it entirely." Id. The Seventh Circuit concluded that the district court had not abused its discretion in denying the motion, given the defendants' concession that the experts' testimony had some relevance and their insistence that they were not trying to exclude the expert testimony entirely. Id.

The defendants also argued that the court should have stricken or excluded the experts' testimony during the trial "once it became clear that the testimony was creating precisely the type of confusion that the motion *in limine* sought to prevent." Id. The defendants argued that the expert testimony "reduce[d] the Government's burden from the standard of criminal intent to the negligence requirement that applies to civil malpractice." Id.

To address this argument, the Seventh Circuit returned to the proof required to convict registered prescribers under §841(a).

> In order to support a violation of the CSA, the jury had to find that the Doctors knowingly and intentionally acted "outside the course of professional practice" and without a legitimate medical purpose." An implementing regulation issued under the CSA, 21 C.F.R. § 1306.04, reiterates this standard: "A prescription for a controlled substance[,] to be effective[,] must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." See, *e.g.*, *United States v. Bek*, 493 F.3d 790, 798 (7th Cir. 2007) ("[T]o convict … a practitioner registered to distribute controlled substances[] of violating § 841(a)(1), the government must show that he prescribed controlled substances outside 'the course of professional practice.'"); see also *United States v. Moore*, 423 U.S. 122, 138-43 . . . (1975). As one court summarized it:
>
> > [T]o convict a practitioner under § 841(a), the government must prove (1) that the practitioner distributed controlled substances, (2) that the distribution of those controlled substances was outside the usual course of professional practice and without a legitimate medical purpose, and (3)

> that the practitioner acted with intent to distribute the drugs *and with intent to distribute them outside the course of professional practice*. In other words, the jury must make a finding of intent not merely with respect to distribution, but also with respect to the doctor's intent to act as a pusher rather than a medical professional.

United States v. Feingold, 454 F.3d 1001, 1008 (9th Cir. 2006).

Id. at 697-98.

Against this backdrop, the Seventh Circuit agreed with the government "that it is impossible sensibly to discuss the question whether a physician was acting outside the usual course of professional practice and without a legitimate medical purpose without mentioning the usual standard of care." Id. at 698. The court conceded that the experts "did not, every time, spell out the fact that something more than conduct below the usual standard of care was needed to show an absence of a valid medical purpose," and noted that at a pretrial motions hearing, the district court had indicated that the government possibly could proceed on a theory that the defendants "didn't do the proper work-up." Id. But the court found that typically during the trial itself, the jury heard from the experts "(1) an opinion from the expert that no legitimate medical purpose existed for the prescription in question; and (2) a clarification from the court that the 'standard of care' is an issue distinct from the question of 'legality.'" Id. The court concluded that the district court did not abuse its discretion in allowing the challenged lines of questioning of the experts and concluded "that a properly instructed jury could keep the relevant concepts straight." Id. at 699.

That led the Seventh Circuit to the defendants' challenge to the jury instructions. The trial court had given the following instructions:

> A controlled substance is prescribed by a physician in the course of his professional practice, and therefore lawfully, if the substance is prescribed by him in good faith in medically treating a patient.
>
> Good faith means good intentions and the honest exercise of good professional judgment as to a patient's medical needs. Good faith means an observance of conduct in accordance with what the physician should reasonably believe to be proper medical care.
>
> In order to determine whether or not a prescription or prescriptions were issued in the course of a defendant physician's professional practice, you may consider all of the evidence of circumstances surrounding the prescribing of the substance in question, the statements of the parties to the prescription transactions, any expert testimony as to what is the usual course of medical practice, and any other competent evidence bearing on the purpose for which the substances in question were prescribed.
>
> Unless you find beyond a reasonable doubt that an act of prescribing charged in the Superseding Indictment was not done in the course of his professional practice, then you should find the defendant you are considering not guilty of the charge you are considering.

Id.

The Seventh Circuit opined that there were "several points at which the instructions make clear that unlawful-distribution liability cannot attach unless no legitimate medical purpose existed for their prescription," including the instructions' elaboration on the meaning of "in the course of professional practice" and "no legitimate medical purpose." Id. The court also observed that the trial court had "permitted defense counsel to draw out the distinctions between the civil and criminal burdens during opening statements, cross-examinations, and closing arguments." Id.

The court then stated,

> Though it is true that the jury instructions did not spell out the distinction between the civil and criminal burdens of proof as expressly as the court did in a case reviewed by the Fourth Circuit, see *United States v. Alerre*, 430 F.3d 681, 687 & n.5 (4th Cir. 2005), there is no one right way to convey the governing standards. This is particularly true where, as here, the defense made no effort even to propose the desired instruction. If it were vital to the defense that the jury receive further clarification on this issue, then the defense should have submitted a proposed instruction.

Id.

The Alerre decision to which the Chube court referred "assess[ed] the proper relationship between the civil and criminal standards of liability for a physician who has prescribed drugs." Alerre, 430 F.3d at 689. The Alerre court indicated that an "enhanced analysis" of the traditional §841(a)(1) elements applied "to persons who are properly registered with the DEA," explaining that under 21 U.S.C. §822, "such persons—including doctors—are authorized to distribute controlled substances to the extent authorized by their registrations." Id. The court discussed the Supreme Court's conclusion in Moore that registered doctors could be held criminally liable under §841 when their activities fell "outside the usual course of professional practice," id. at 690 (quoting Moore, 423 U.S. at 124), then explained that "[i]n discussing the proper application of the criminal standard, we have observed that 'a licensed physician who prescribes controlled substances outside the bounds of his professional medical practice is subject to prosecution and is no different than a large-scale pusher,'" id. (citing United States v. Tran Trong Cuong, 18 F.3d 1132, 1137 (4th Cir. 1994)). The court contrasted that with the South Carolina standard for civil medical malpractice, where a plaintiff must show "(1) 'the

generally recognized practices and procedures that would be exercised by competent practitioners in a defendant doctor's field of medicine under the same or similar circumstances,' and (2) 'that the defendant doctor departed from the recognized and generally accepted standards, practices, and procedures.'" Id. (quoting Gooding v. St. Francis Xavier Hosp., 487 S.E.2d 596, 599 (1997)).

The Alerre court explained that in Tran Trong Cuong, it had

> observed that a criminal prosecution requires "proof beyond a reasonable doubt that the doctor was acting outside the bounds of professional medical practice." *Tran Trong Cuong*, 18 F.3d at 1137. [The Tran Trong Cuong decision] elaborated that, in such a situation, a physician's authority to prescribe drugs is being used "not for treatment of a patient, but for the purpose of assisting another in the maintenance of a drug habit or of dispensing controlled substances for other than a legitimate medical purpose, i.e. the personal profit of the physician." *Id.* We concluded that the instructions in Tran's trial not only comported with the criminal standard, but also required the prosecution to prove that the physician had written prescriptions "without a legitimate medical purpose," arguably a more stringent requirement then the criminal standard announced in *Moore*, inuring "to [the] defendant's benefit." *Id.* at 1137-38.

Id. at 690-91.

The Alerre court then turned to the defendants' arguments that the lawyers—prosecution and defense—had "erroneously conflated the criminal standard with the civil standard and that, as a result, they were tried and convicted for civil malpractice rather than for the criminal distribution of drugs." Id. at 691. The trial court had given several jury instructions, including an instruction that the jury "could not convict on the distribution and drug conspiracy charges if it found only that the defendants' practices fell 'below

that line of what a reasonable physician would have done.'" Id. at 687. The court told the jury that "in order to convict on the distribution and drug conspiracy charges, the jury was obliged to find beyond a reasonable doubt that the defendants were selling drugs, or conspiring to do so, and not practicing medicine." Id.

The appellate court noted that the trial court had given the same jury instructions as the ones the Fourth Circuit had approved in the Tran Trong Cuong case, but that it had "more clearly articulated the distinction between the civil standard and the criminal standard." Id. at 691 n.9. It noted that the trial court had "cautioned the jury about the standard-of-care evidence" and "explained the degree of proof (i.e., proof beyond a reasonable doubt) necessary for a criminal conviction." Id.

The Fourth Circuit quoted the "standard-of-care" instruction the trial court had given:

> There has been some mention … of the standard of care. I'm not so sure the word[] malpractice ha[s] not been used. Those words relate to civil actions. When you see a doctor, as a patient, that doctor must treat you in a way so as to meet the standard of care that physicians of similar training would have given you under the same or similar circumstances….
>
> That's not what we're talking about. We're not talking about these physicians acting better or worse than other physicians. We're talking about whether or not these physicians prescribed a controlled substance outside the bounds of their professional practice.

Id. at 687 n.5. It also explained that

> [t]he court further instructed the jury that "[i]f you find that a defendant acted in good faith in dispensing the drugs charged …, then you must find that defendant not guilty." J.A. 1298. The court

> then addressed the standard-of-care evidence and instructed the jury that the critical issue on the distribution and drug conspiracy charges was not whether the defendants had acted negligently, but "whether or not these physicians prescribed a controlled substance outside the bounds of their professional practice.' J.A. 1299.

Id. at 691 n.9.

In responding to the defendants' argument that the lawyers improperly conflated criminal and civil standards and thus that they were convicted of malpractice, the Fourth Circuit concluded that "the jury was correctly instructed on the applicable legal principles." Id. at 692. The appellate court stated that

> [t]he trial court was careful to spell out the differences between the criminal standard and the civil standard. Indeed, it admonished the jury that the defendants could only be convicted under the criminal standard, and it emphasized that they could not be convicted if they had dispensed the controlled substances at issue "in good faith."

Id.

The instructions the Fourth Circuit had approved in Tran Trong Cuong were as follows:

> The third element, no legitimate medical purpose. The final element the government must prove beyond a reasonable doubt is that the defendant prescribed the drug other than for legitimate medical purpose and not in the usual course of medical practice.
>
> In making a medical judgment concerning the right to treatment for an individual patient physicians have discretion to choose among the wide range of available options. Therefore, in determining whether defendant acted without a legitimate medical purpose, you should examine all the defendant's actions and the circumstances surrounding them.
>
> For example, evidence that a doctor warns his patients to fill their prescription at different drug stores, prescribes drugs without performing any physical examinations or only very superficial ones, or ask [sic] patients about the amount or type of drugs they want,

> may suggest that the doctor is not acting for a legitimate medical purpose other than a [sic] outside the usual course of medical practice. These examples are neither conclusive nor exhaustive. They are simply meant to give you an idea of the kind of behavior from which you may conclude that a doctor was not prescribing drugs for a legitimate medical purpose and was not acting in the usual course of medical practice.
>
> A doctor dispenses a drug in good faith in medically treating a patient, then the doctor has dispensed the drug for a legitimate medical purpose in the usual course of medical practice. That is, he has dispensed the drug lawfully. Good faith in this context means good intentions in the honest exercise of best professional judgment as to a patient's need. It means the doctor acted in accordance with what he believed to be proper medical practice.[3]
>
> If you find the defendant acted in good faith in dispensing the drug, then you must find him not guilty.

Tran Trong Cuong, 18 F.3d 1132, 1137-38 (4th Cir. 1994).

The Seventh Circuit again had occasion to discuss the elements of unlawful prescription of controlled substances in 2012 when it decided United States v. Pellman, 668 F.3d 918 (7th Cir. 2012). Pellman, a medical doctor, was convicted of distributing fentanyl in violation of §841(a)(1). Id. at 919. In addressing Pellman's argument that the government was required to introduce expert testimony to prove the elements of the unlawful prescription charges, the Seventh Circuit reviewed what the government was required to prove:

> Typically, to convict a person of violation 21 U.S.C. § 841(a)(1), the government must establish that the defendant knowingly possessed with an intent to distribute a controlled substance, and that the defendant knew that the substance was controlled. *See United*

[3] In its opposition to Lisa Hofschulz's proposed elements instruction, the government asks that if the court "believes that the proposed instructions are unclear as to the third element," it add language suggested by 3 Leonard B. Sand, *et al.*, *Modern Federal jury Instructions*, Instruction 56-18. Dkt. No. 115 at 33. The government then quotes almost identical language to the language used by the Tran Trong Cuong court.

> *States v. Bek*, 493 F.3d 790, 798 (7th Cir. 2007). Where the defendant is a physician, however, the government must also show that he prescribed controlled substances (1) "outside the course of professional practice" and (2) without a "legitimate medical purpose." *Id.*; *see also United States v. Chube*, 538 F.3d 693, 697-98 (7th Cir. 2008); 21 C.F.R. § 1306.04(a) ("A prescription for a controlled substance[,] to be effective[,], must be issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice.").

Id. at 923-24.

Most recently, the Seventh Circuit addressed the jury instruction issue in United States v. Kohli, 847 F.3d 483 (7th Cir. 2017). The defendant—an Illinois physician who specialized in pain management—was convicted on several counts of "prescribing narcotics without a legitimate medical purpose in violation of § 841(a) of the Controlled Substances Act." Id. at 486. He argued on appeal that he was entitled to an acquittal "because the evidence did not establish that he intentionally engaged in any unlawful conduct." Id. at 489. In analyzing that argument, the Seventh Circuit recited the elements of the offense:

> To convict a prescribing physician under § 841(a) of the Controlled Substances Act, the government must prove that the physician knowingly prescribed a controlled substance outside the usual course of professional medical practice and without a legitimate medical purpose. *United States v. Pellmann*, 668 F.3d 918, 923, (7th Cir. 2012); *Chube II*, 538 F.3d at 698; 21 C.F.R. § 1306.04(a). In other words, the evidence must show that the physician not only intentionally distributed drugs but that he intentionally "act[ed] as a pusher rather than a medical professional." See *Chube II*, 538 F.3d at 698; see also *United States v. Moore*, 423 U.S. 122, 138-43 . . . (1975).

Id. at 489-90.

After concluding that the government had presented "ample evidence establishing that Dr. Kohli intentionally abandoned his role as a medical professional and unlawfully dispensed controlled substances with no legitimate medical purpose," the court addressed Dr. Kohli's argument that because the evidence showed he gave the prescriptions to patients "who suffered from documented medical conditions associated with chronic pain" and that the evidence showed that those patients "exhibited addictive behaviors," "the jury must have convicted him on the erroneous belief that the Controlled Substances Act categorically criminalizes prescribing narcotics to patients who happen to suffer from addiction disorder in addition to chronic pain." Id. at 490. The appellate court described this argument as missing the mark.

> The issue before the jury was not simply whether Dr. Kohli prescribed narcotics to drug addicts. That, in itself, is certainly not a violation of the Controlled Substances Act. Rather, the issue was whether he deliberately prescribed outside the bounds of medicine and without a genuine medical basis.
>
> * * * * *
>
> To be clear, we agree with Dr. Kohli that physicians are not automatically liable under § 841(a) whenever they prescribe narcotics to a patient who happens to be addicted; but we add that neither are they automatically immune from liability whenever a patient who is obviously misusing their prescription happens to suffer from chronic pain. The Controlled Substances Act does not give physicians carte balance to prescribe controlled drugs for a non-medical purpose simply because the immediate recipient of the prescription has an illness that the drugs could in theory alleviate if used properly. In every case, the critical inquiry is whether the relevant prescriptions were made for a valid medical purpose and within the usual course of professional practice. Here, a jury could reasonably conclude that they were not.

Id. at 490-91 (footnote omitted).

The court also rejected the defendant's argument that the district court erred in allowing the government's expert to testify about "applicable legal standards." Id. at 491. The court noted that the expert "testified that he believed certain of Dr. Kohli's prescriptions were inconsistent with the usual course of professional practice and lacked a legitimate medical purpose." Id. The Seventh Circuit concluded "that testimony tracks the elements necessary to sustain a conviction for illegal dispensation, see 21 C.F.R. § 1306.04(a)," and that while that testimony embodied an opinion about a dispositive issue in the case, such opinions are allowed under Fed. R. Evid. 704(a). Id. The court similarly rejected the defendant's argument challenging the expert's testimony about the applicable legal standard:

> It is true that Dr. Parran's testimony touched on the applicable standard of care among medical professionals—a standard that is no doubt closely linked to § 841(a)'s prohibition on prescribing outside the "usual course of professional medical practice." But testimony on the standard of care is not converted into an impermissible jury instruction on the governing legal standard just because the two standards overlap. If that were the case, physicians could virtually never offer meaningful expert opinions in prosecutions under § 841(a). See *Chube II*, 538 F.3d at 698 (recognizing that "it is impossible sensibly to discuss the question whether a physician was acting outside the usual course of professional practice and without a legitimate medical purpose without mentioning the usual standard of care"). Dr. Parran did not lecture the jury about the legal meaning or application of § 841(a), but simply opined that certain of Dr. Kohli's actions were medically unjustified and contrary to standard professional medical practice. That opinion was within Dr. Parran's area of expertise and was not inappropriate under Rule 704 or otherwise.

Id. at 492.

Finally, Dr. Kohli argued on appeal that "the district court erroneously instructed the jury that a finding of civil malpractice was sufficient to support a

conviction." Id. at 494. Dr. Kohli's counsel did not object to the jury instructions at the time the trial court gave them, so the Seventh Circuit reviewed them for plain error. Id. It found no such error:

> The court instructed the jury to convict Dr. Kohli of illegally dispensing controlled substances under § 841(a) only if the jury found, beyond a reasonable doubt, that Dr. Kohli (1) knowingly and intentionally prescribed controlled substances (2) outside the usual course of professional medical practice, and (3) for no legitimate medical purpose. That is exactly what the statute requires to support a conviction. See 21 U.S.C. § 841(a); 21 C.F.R. § 1306.04(a). The district court thus correctly spelled out each of the elements of the offense, and clearly articulated the appropriate burden of proof governing criminal liability. The court further instructed the jury that it should *not* convict Dr. Kohli if it found that he made the relevant prescriptions in good faith.
>
> We see no support for Dr. Kohli's argument that the district court somehow conflated the standards for civil and criminal liability, or that it otherwise misled the jury into believing that it could find Dr. Kohli criminally liable for engaging in mere civil malpractice. The district court's jury instructions fairly and accurately stated the law and do not warrant reversal.

Id.

The following are the instructions that the Kohli trial court gave the jury:

> In order for you to find the Defendant guilty of a charge of causing the illegal dispensation of a Schedule II controlled substance, the Government must prove the following elements beyond a reasonable doubt as to the charge that you are considering:
>
> 1: That the Defendant knowingly caused to be dispensed the controlled substance alleged in the charge you are considering;
>
> 2: That the Defendant did so by intentionally prescribing the controlled substance outside the usual course of professional medical practice, and not for legitimate medical purpose; and
>
> 3: That the Defendant knew that the substance was some kind of a controlled substance.

If you find from your consideration of all the evidence that the Government has proved each of these elements beyond a reasonable doubt as to the charge you are considering, then you should find the Defendant guilty of that charge. If, on the other hand, you find from your consideration of all the evidence that the Government has failed to prove any one of these elements beyond a reasonable doubt as to the charge you are considering, then you should find the Defendant not guilty of that charge.

The term dispense means to deliver a controlled substance to the ultimate user by or pursuant to the lawful order of a practitioner. The term *practitioner* means a physician or other person licensed, registered, or otherwise permitted by the United States to distribute, dispense or administer a controlled substance in the course of professional practice.

With respect to the charges of causing illegal dispensation of a controlled substance in Counts 4 through 13, the Government must prove beyond a reasonable doubt that the Defendant caused to be dispensed to the patient the specific controlled substance while acting outside the usual course of professional medical practice and not for legitimate medical purpose. A physician's own treatment methods do not themselves establish what constitutes professional medical practice. In determining whether Defendant's conduct was outside the usual course of professional medical practice, you should consider the testimony you have heard relating to what has been characterized during the trial as the norms of professional practice. You should consider the Defendant's actions as a whole, the circumstances surrounding them, and the extent of severity of any violations of professional norms you find the Defendant may have committed.

With respect to charges of causing the illegal dispensation of a controlled substance in Counts 4 through 13, the Defendant may not be convicted if he dispenses or causes to be dispensed controlled substances in good faith to patients in the usual course of professional medical practice. Only the lawful acts of a physician, however, are exempted from prosecution under the law. The Defendant may not be convicted if he merely made an honest effort to treat his patients in compliance with an accepted standard of practical practice.

A controlled substance is dispensed or caused to be dispensed by a physician in the usual course of his professional medical practice, and, therefore, lawfully if the substance is dispensed or caused to be dispensed by him in good faith in medically treating a

> patient. Good faith in this context means good intentions and the honest exercise of good professional judgment as to the patient's medical needs.
>
> Good faith means an observance of conduct in accordance with what the physician should reasonably believe to be proper medical practice.
>
> In determining whether the Defendant acted in good faith in the usual course of professional medical practice, you may consider all the evidence in the case which relates to that conduct.

United States v. Kohli, Case No. 14-cr-40038-JPG (S.D. Ill.), Dkt. No. 173 at Page ID #5121-23.

2. *Elements Instruction*

The government opposes the elements instruction proposed by Lisa Hofschulz, arguing that it "adds a *mens rea* component as a separate element." Dkt. No. 115 at 33. The government argues that the defendant's "proposed addition of a fourth element is confusing and unnecessary." Id. And it asserts that the version of the instruction it has proposed is the version the Seventh Circuit affirmed in Kohli (and that that version is "the same as provided for in 3 Leonard B. Sand et al., Modern Federal Jury Instructions, Instruction 56-15."). Id. at 32. In support of her version, Lisa Hofschulz cites United States v. Szyman, Case No. 16-cr-95 (E.D. Wis.), Dkt. No. 49 at 6-7. Id.

The instruction that the government proposes is not identical to the instruction the trial court gave in Kohli (and that the Seventh Circuit said was "exactly what the statute required to support a conviction"). The government's version of the second element—the element regarding prescribing outside of the usual course of professional medical practice and not for a legitimate

purpose—omits one word that the Kohli instruction included: "intentionally." Dkt. No. 115 at 23. The government proposes the following as the second element:

> that the defendant did so by prescribing the controlled substance(s) outside of the usual course of professional medical practice and not for a legitimate medical purpose;

id., while the Kohli court gave the following as the second element:

> That the Defendant did so by *intentionally* prescribing the controlled substance outside the usual course of professional medical practice, and not for legitimate medical purpose.

Kohli, Case No. 14-cr-40038-JPG, Dkt. No. 173 at Page ID #5121 (emphasis added).

It is appropriate to reference the *mens rea* requirement in the "outside of the usual course and not for a legitimate medical purpose" element. Section 841(a) states that it is unlawful for anyone to "knowingly and intentionally" engage in the activities it describes. Both the government and Lisa Hofschulz include the "knowingly" requirement in the language of the other two elements; each phrases the instruction as requiring the government to prove that the defendant "knowingly" distributed or dispensed the controlled substance, and to prove that the defendant "knew" that the substance was some sort of controlled substance. The government has not explained why the same should not be true for the "outside of the usual course and not for a legitimate medical purpose" element, particularly when the Seventh Circuit has found that a version of the element that contained the "intentionally" language was "exactly" what the statute required to support a conviction.

The Seventh Circuit also has implied in one decision and stated in another that the "outside of the usual course and not for legitimate medical purpose" element is subject to the same *mens rea* requirement as the other two elements. In Chube II, the court referenced the Ninth Circuit's decision in Feingold, in which it stated that to sustain a conviction, the government must prove

> that the practitioner acted with intent to distribute the drugs *and with intent to distribute them outside the course of professional practice*. In other words, the jury must make a finding of intent not merely with respect to distribution, but also with respect to the doctor's intent to act as a pusher rather than a medical professional.

Chube II, 538 F.3d at 697-98 (quoting Feingold, 454 F.3d at 1008). And in Kohli, the court explicitly stated that to convict a prescriber under §841(a), the government "must prove that the physician knowingly prescribed a controlled substance outside the usual course of professional medical practice and without a legitimate medical purpose" and clarified that the "evidence must show that the physician not only intentionally distributed drugs but that he intentionally 'act[ed] as a pusher rather than a medical professional.'" Kohli, 847 F.3d at 489-90 (citing Chube II, 538 F.3d at 698; Moore, 423 U.S. at 138-43).

Teasing out the *mens rea* requirement and stating it as a fourth, separate element as Lisa Hofschulz proposes, however, does not make sense. If two of the elements already contain a *mens rea* requirement, adding a separate *mens rea* requirement after the first three elements would be redundant as to the two elements that already include that requirement. It makes more sense to include

the *mens rea* requirement in the "outside the usual course and without legitimate medical purpose requirement," just as it is included in the other two elements.

The court will give a version of the elements instruction that the Kohli court gave:

> For you to find a defendant guilty of distributing and dispensing a controlled substance, the government must prove the following elements beyond a reasonable doubt as to the defendant and the charge that you are considering:
>
> First, that that defendant knowingly caused to be distributed or dispensed the controlled substance alleged in the charge you are considering;
>
> Second, that that defendant did so by intentionally distributing or dispensing the controlled substance outside the usual course of professional medical practice, and not for legitimate medical purpose; and
>
> Third, that that defendant knew that the substance was some kind of a controlled substance.
>
> If you find from your consideration of all the evidence that the government has proved each of these elements beyond a reasonable doubt as to the defendant and the charge you are considering, then you should find that defendant guilty of that charge. If, on the other hand, you find from your consideration of all the evidence that the government has failed to prove any one of these elements beyond a reasonable doubt as to the defendant and the charge you are considering, then you should find the defendant not guilty of that charge.

The government has asked that if the court "believes that [its] proposed instructions are unclear as to the third element," the court include three paragraphs suggested by 3 Leonard B. Sand, *et al.*, *Modern Federal Jury Instructions*, Instruction 56-18. Dkt. No. 115 at 33. Lisa Hofschulz included one of those paragraphs in her proposed good faith instruction:

> In making a medical judgment concerning the right treatment for a patient, [prescribers] have discretion to choose among a wide range of available options. Therefore, in determining whether the defendant acted without a legitimate medical purpose, you should examine all of the defendant's actions and the circumstances surrounding them.

Id. at 33, 35. The Fourth Circuit approved this instruction in Tran Trong Cuong and Alerre. Because it appears that both the government and the defense want this instruction, and because it does not contradict Supreme Court or Seventh Circuit law, the court will include this paragraph.

As to the second paragraph the government seeks—a paragraph describing all the ways in which a prescriber might act not for a legitimate medical purpose and outside the course of professional medical practice—the court will withhold judgment on whether to include it. It is not common for jury instructions to describe specific illegal behavior. In a traditional §841(a)(1) prosecution, the court does not instruct the jury that "evidence that a person talks in code during telephone conversations, has a hidden compartment in his car, possesses large amounts of unexplained cash, or possesses gram-weight scales and packaging materials may suggest that the person is illegally selling controlled substances." The government is free to make those arguments, and the defense to rebut them, but it is the jury's responsibility to decide whether those actions are outside the course of professional medical practice and not for a legitimate medical purpose.

3. *Definition of Knowingly*

The government has proposed Seventh Circuit pattern instruction 4.10, while Lisa Hofschulz proposes to add to that instruction the sentence, "In the

context of this case, this means that the government must prove beyond a reasonable doubt that Lisa Hofschulz knew that her prescribing of the controlled substance at issue was both outside the usual course of medical practice and not for a legitimate medical purpose." Dkt. No. 115 at 34. The court will give the Seventh Circuit pattern instruction and will not include the sentence Lisa Hofshulz has proposed.

The court has determined that it will include the word "intentionally" in the "outside the usual course of medical practice and not for a legitimate medical purpose" instruction. The inclusion of that *mens rea* requirement will reiterate for the jury that it must find that the defendant intended to distribute or dispense the controlled substance outside the usual course of medical practice and not for a legitimate medical purpose. Stating the same as part of the definition of "knowingly" is redundant. Further, the inclusion of the language Lisa Hofschulz proposes would render the "knowingly" definition inapplicable to co-defendant Robert Hofschulz, who also has been charged with unlawfully prescribing controlled substances.

The court notes that the first paragraph of pattern instruction 4.10 includes alternative language in brackets. That language reads, "In deciding whether the defendant acted knowingly, you may consider all of the evidence, including what the defendant did or said." The William J. Bauer Pattern Criminal Jury Instructions of the Seventh Circuit (2020 Ed.), Instruction 4.10. The court usually includes that bracketed language, and in this case, including

that language comports with the instructions the trial courts gave in Chube II and Kohli.

4. *Good Faith*

a. Robert Hofschulz's proposed instruction

Robert Hofshulz has asked the court to give Seventh Circuit Pattern Instruction 6.11, entitled "Good Faith." Dkt. No. 115 at 29. The Committee Comment to this instruction states:

> When a defendant is accused of violating a complex and technical statute, such as a criminal tax statute, the term "willfully" has been construed to require proof that the defendant acted with knowledge that his conduct violated a legal duty. *Ratzlaf v. United States*, 510 U.S. 135, 144-46 (1994); *Cheek v. United States*, 498 U.S. 192, 201 (1991); *United States v. Wheeler*, 540 F.3d 683, 689 (7th Cir. 2008); *United States v. Murphy*, 469 F.3d 1130, 1138 (7th Cir. 2006).

Robert Hofshulz argues that because he had no medical training and did not author any prescriptions, he is entitled to "this discussion in order to treat the case as a whole fairly and accurately as it applies to him." Dkt. No. 115 at 29. He cites United States v. Koster, 163 F.3d 1008 (7th Cir. 1998) in support of his request.

The court will not give Seventh Circuit Pattern Instruction 6.11. The instruction, as both its title and the Committee Comment make clear, is designed to be given in cases involving alleged violations of complex technical statutes, and in cases in which the *mens rea* requirement is "willful" action. The grand jury did not charge Robert Hofschulz with violating a criminal tax statute or some other complex, "technical" statute—it has charged him with

conspiring to unlawfully distribute and prescribe controlled substances and unlawfully distributing such substances. The *mens rea* requirement for violations of 21 U.S.C. §841 is "knowingly and intentionally," not "willfully."

The Koster case does not persuade the court otherwise. Koster involved a thirty-count indictment charging the defendant with defrauding the Commodity Credit Corporation. Id. at 1009. As the government points out, the district court refused to give a good faith instruction in Koster; the Seventh Circuit affirmed, finding that the *mens rea* requirements in the instructions regarding the elements of the crimes with which the defendant had been charged encompassed a good faith defense, because "[a]n action taken in good faith is the other side of an action taken knowingly." Id. at 1012 (citing United States v. Schwartz, 787 F.2d 257, 265 (7th Cir. 1986)).

b. Lisa Hofschulz's proposed instruction

The government has agreed that the court should give a good faith instruction and as evidenced from the discussion of the governing case law, such instructions are common in unlawful prescription cases. The parties dispute the content of the instruction.

The portions of Lisa Hofschulz's proposed instruction to which the government most vehemently objects are the following:

> If you find that Lisa Hofschulz acted in good faith, that would be a complete defense for these charges because good faith on the part of Lisa Hofschulz would be inconsistent with her acting knowingly and intentionally. A person acts in good faith when he or she has an honestly held belief of the truth of the statements being given to them even though the belief turns out to be inaccurate or incorrect.

Dkt. No. 115 at 35. The next paragraph of the proposed instruction says that "[g]ood faith is a defense because it is inconsistent with the requirement of the offenses that she acted knowingly and intentionally." Id. These portions reflect a subjective good faith standard; the instruction tells the jury that if Lisa Hofshulz believed that what she was doing was right for a particular patient, she could not be found guilty of unlawfully prescribing to such a patient—even if what she was doing was outside the course of professional medical conduct and was not for a legitimate medical purpose.

The government argues that the circuit courts that have considered the good faith defense as it relates to unlawful prescription cases all have concluded that the good faith defense is subject to an *objective*, not a *subjective*, standard and cites cases from five circuits holding as much. In 2006, the Fourth Circuit agreed with the defendant doctor that good faith "generally" was relevant to a jury's determination of whether a doctor acted outside the bounds of medical practice and with a legitimate medical purpose. United States v. Hurwitz, 459 F.3d 463, 476 (4th Cir. 2006). But the good faith instruction the defendant in Hurwitz had proposed defined good faith as meaning "the doctor acted according to what *he believed to be proper medical practice*." Id. at 478. The Fourth Circuit stated, "This proposed instruction clearly sets forth a subjective standard, permitting Hurwitz to decide for himself what constitutes proper medical treatment." Id. The court concluded that the instruction was improper, opining that "allowing criminal liability to turn on whether the defendant-doctor complied with his own idiosyncratic view

of proper medical practices is inconsistent with the Supreme Court's decision in *Moore*." Id.

The Fourth Circuit since has reiterated that holding in United States v. Purpera, 844 F. App'x 614, 626 (4th Cir. 2021), rejecting a proposed good faith instruction that defined good faith as meaning that "the doctor acted in accordance with (what he reasonably believed to be) the standard of medical practice generally recognized and accepted in the United States." The court stated that, like the instruction it had rejected in Hurwitz, the Purpera instruction "permits a doctor 'to decide for himself what constitutes proper medical treatment,' thereby setting forth a standard for good faith that is entirely subjective." Id. at 627.

The Purpera court explained that the defendant had asserted that his proposed instruction was similar to one the Sixth Circuit had approved in United States v. Voorhies, 663 F.2d 30, 34 (6th Cir. 1981), which "defined good faith as 'an observance of conduct in accordance with what the physician *should* reasonably believe to be proper medical practice.'" Id. (quoting Voorhies, 663 F.2d at 34). The Fourth Circuit characterized the Voorhies instruction as "meaningfully different from one that is based on what the physician *actually* believed." Id. It explained that "[a] jury tasked with assessing what a physician *should have* believed must apply an objective standard," while "determining what a doctor *actually* believed requires a jury to assess the doctor's subjective point of view." Id.

The Eleventh Circuit reached the same conclusion in United States v. Williams, 445 F.3d 1302, 1309 (11th Cir. 2006) and United States v. Merrill, 513 F.3d 1293 (11th Cir. 2008). In Merrill, the defendant had proposed an instruction that focused on the defendant doctor's subjective intent; in rejecting the defendant's argument that the district court should have given his instruction, the Eleventh Circuit stated:

> We have already indicated that a good faith instruction focusing on the physician's subjective intent, like the one proposed by Merill, "fails to introduce any objective standard by which a physician's prescribing behavior can be judged." *United States v. Williams*, 445 F.3d 1302, 1309 (11th Cir. 2006), *abrogated on other grounds*, *United States v. Lewis*, 492 F.3d 1219 (11th Cir. 2007) (en banc).
>
> The appropriate focus is not on the subjective intent of the doctor, but rather it rests on whether the physician prescribes medicine "in accordance with a standard of medical practice generally recognized and accepted in the United States." *Id.* (quoting *United States v. Moore*, 423 U.S. 122, 139 . . . (1975)). In *Williams*, we affirmed a trial court's instruction like the one given here which focuses on whether the doctor acted in accordance with a generally-accepted standard of medical practice. Therefore, we find that the district court neither committed plain error nor abused its discretion in not giving Merill's proposed jury instruction.

Merrill, 513 F.3d at 1306.

In United States v. Wexler, 522 F.3d 194 (2d Cir. 2008), the defendant asked the trial court to include language in the instructions regarding "good intentions," arguing, "If you have good intentions, it doesn't matter if you made a mistake. It only matters if you didn't have good intentions." Wexler, 522 F.3d at 205. The district court declined to include the language the defendant requested, opining that "good intentions is too loosey goosey a formulation and will lead to juror confusion." Id. The Second Circuit found that the district

court did not err in refusing to include the requested language, stating in part that "the inclusion of a good-intentions component of good faith may very well contradict the objective standard of reasonableness required for a finding of good faith." Id. at 206.

In United States v. Smith, 573 F.3d 639, 647 (8th Cir. 2009), the defendant argued that the language of 21 C.F.R. §1306.04—requiring that for a prescription to be effective, it must be issued "for a legitimate medical purpose by an individual practitioner acting in the usual course of *his* professional practice" (emphasis added)—meant that "'his professional practice' [was] to be judged with reference to the particular practices of the issuing doctor, as opposed to generally accepted medical practices." The Eighth Circuit disagreed, finding that the physician's practice "must still comport with the tenants of medical professionalism." Id. at 648. The court stated, referencing its own precedent, that "[w]e are . . . not at liberty to eliminate the requirement that an issuing practitioner's practice be objectively 'professional,' even assuming that we are required by the regulation to consider 'his' particular practice." Id. (citing Moore, 423 U.S. at 140-43; referencing United States v. Katz, 445 F.3d 1023 (8th Cir. 2006)). It concluded that it was "not improper to measure the 'usual course of professional practice' under § 841(a)(1) and § 1306.04 with reference to generally recognized and accepted medical practices and not a doctor's self-defined particular practice," noting that the defendant's proposed interpretation "would allow an individual doctor to define the parameters of his or her practice and effectively shield the practitioner from criminal liability

despite the fact that the practitioner may be acting as nothing more than a 'large-scale pusher.'" Id. at 648-49 (citing Moore, 423 U.S. at 143).

A defendant had put forward this same interpretation of §1306.04(a) years earlier in United States v. Norris, 780 F.2d 1207 (5th Cir. 1986). The Fifth Circuit—as would the Eighth Circuit twenty years later—rejected the argument, succinctly stating that "[o]ne person's treatment methods do not alone constitute a medical practice," and finding that the trial court "correctly rejected Norris' proposed charge premised on a theory that a standard medical practice may be based on an entirely subjective standard." Id. at 1209.

In Purpera, the Fourth Circuit discussed the Sixth Circuit's ruling in Voorhies. Twenty-eight years later, the Sixth Circuit reiterated its ruling from Voorhies. In United States v. Godofsky, 943 F.3d 1011, 1015 (6th Cir. 2019), the defendant requested a good faith instruction that defined good faith as meaning that "the defendant acted in accordance with what he reasonably believed to be proper medical practice." Id. at 1016. The trial court refused to give that instruction—in fact, refused to give a good faith instruction at all. Id. at 1017. The Sixth Circuit characterized the defendant's argument in support of the instruction as an argument that "even though he knowingly an intentionally violated professional medical practices and prescribed oxycodone for no legitimate medical purpose (as the jury found), he cannot be convicted because he personally believes that such unprofessional and illegitimate actions were nonetheless beneficial to his patients." Id. at 1026. The Sixth Circuit rejected that argument, stating "that is not the law." Id.

This court agrees with these circuit courts—whether a defendant charged with unlawfully prescribing controlled substances acted in good faith must be determined using an *objective* standard, not a subjective one. The subjective standard Lisa Hofschulz proposes does not comport with Moore, and as some of the courts above have noted, it would nullify §1306.04(a) by allowing each individual prescriber to decide the "course of professional medical practice."

More broadly, the instructions proposed by the government contain, for the most part, language that either the Supreme Court or the Seventh Circuit has found does not constitute error. The court recounts the government's instructions below, and where applicable, identifies the source of the language; the government's proposed language is italicized and the matching language from Supreme Court or Seventh Circuit case law is in bold.

Outside the Usual Course of Professional Medical Practice and Not for a Legitimate Purpose (Dkt. No. 115 at 24)

> *Federal law authorizes registered medical practitioners to dispense a controlled substance by issuing a lawful prescription.*
>
> "**Federal law authorizes** a licensed physician **to** prescribe **controlled substances** of the kinds charged in the indictment, if the drug is prescribed in the course of the physician's professional practice." Green, 511 F.2d at 1071 n.22.
>
> *Registered practitioners are exempt from criminal liability if they distribute or dispense controlled substances for a legitimate purpose while acting in the usual course of professional practice. A registered practitioner violates Section 841(a)(1) of Title 21 of the United States Code if the practitioner distributes or dispenses a controlled substance without a legitimate medical purpose and outside the usual course of standard medical practice.*
>
> [The court could find no matching language for this portion of the instruction in any of the cases discussed above.]

A prescriber's own treatment methods do not themselves establish what constitutes professional medical practice. In determining whether the defendant's conduct was outside the usual course of professional medical practice, you should consider the testimony you have heard relating to what has been characterized during the trial as the norms of professional practice. You should consider the defendant's actions as a whole, the circumstances surrounding them, and the extent of severity of any violations of professional norms you find the defendant may have committed.

"**A** physician's **own treatment methods do not themselves establish what constitutes professional medical practice. In determining whether Defendant's conduct was outside the usual course of professional medical practice, you should consider the testimony you have heard relating to what has been characterized during the trial as the norms of professional practice. You should consider the Defendant's actions as a whole, the circumstances surrounding them, and the extent of severity of any violations of professional norms you find the Defendant may have committed**." Kohli, Case No. 14-cr-40038-JPG (S.D. Ill.), Dkt. No. 173 at Page ID #5122. See also, Bek, 493 F.3d at 798-99 ("**[i]n determining whether the defendant's conduct was within the bounds of professional medical practice, you should consider the testimony you have heard relating to what has been characterized during trial as the 'norms' of professional practice**.").

Good Faith in the Usual Course of Professional Medical Practice (Dkt. No. 115 at 25)

The Defendant may not be convicted if she dispenses or causes to be dispensed controlled substances in good faith in accordance with the standards of professional medical practice generally recognized and accepted in the United States.

"**[T]he Defendant may not be convicted if he dispenses or causes to be dispensed controlled substances in good faith** to patients in the usual course of professional medical practice." Kohli, Case No. 14-cr-40038-JPG (S.D. Ill.), Dkt. No. 173 at Page ID #5123.

The jury must find "beyond a reasonable doubt that a physician, who knowingly or intentionally did dispense or distribute methadone) by prescription, did so other than in good faith for detoxification in the usual course of a professional practice and **in accordance with a standard of medical practice generally**

recognized and accepted in the United States." Moore, 423 U.S. at 138-39.

Only the lawful acts of a prescriber, however, are exempted from prosecution under the law.

"Only the lawful acts of a physician**, however, are exempted from prosecution under the law."** Kohli, Case No. 14-cr-40038-JPG (S.D. Ill.), Dkt. No. 173 at Page ID #5123.

Good faith in this context means an observance of conduct in accordance with what the prescriber should reasonably believe to be proper medical practice defined by generally recognized and accepted standards of professional medical practice.

"**Good faith means an observance of conduct in accordance with what the** physician **should reasonably believe to be proper medical** care." Chube II, 538 F.3d at 699.

In determining whether the defendant acted in good faith in the usual course of professional medical practice, you may consider all of the evidence in the case which relates to that conduct.

"In determining whether the Defendant acted in good faith in the usual course of professional medical practice, you may consider all the evidence in the case which relates to that conduct." Kohli, Case No. 14-cr-38-JPG (S.D. Ill.), Dkt. No. 173 at Page ID #5123.

While some of the language in the government's proposed instructions may be duplicative of the elements instruction, the government's proposed instructions generally comport with the law in this circuit. As far as the court can tell, neither the Supreme Court nor the Seventh Circuit has addressed the instruction proposed by Lisa Hofschulz, and as the court has explained, much of that instruction incorrectly states the law. The court will not give the good faith instruction proposed by Lisa Hofschulz.

5. *Standard of Care*

The discussion of the governing law reveals that in some unlawful prescription cases, events at trial prompted the defendants to argue on appeal that the jury might have thought it was being called upon to decide whether the defendant was liable for civil malpractice, rather than for criminal conduct. In at least one case, the language used by the government's expert was the basis for that argument. In another, language used by the court at a pretrial conference gave rise to the concern. Perhaps the language used by the lawyers in questioning and arguing gave rise to the concern.

Under Wisconsin law, a civil claim for medical malpractice "requires the following four elements: (1) a breach of (2) a duty owed (3) that results in (4) an injury or injuries, or damages. . . . In short, a claim for medical malpractice requires a negligent act or omission that causes an injury." Paul v. Skemp, 242 Wis. 2d 507, 520 (Wis. 2001).

As required by §1306.04(a), the elements instruction the court has agreed to give requires the government to prove beyond a reasonable doubt that the defendant distributed or dispensed controlled substances "outside the usual course of professional practice and not for a legitimate medical purpose." It does not mention breach or duty or injury or damages. The cases described in this decision did not involve defendants who made a one-time mistake; they involve defendants who repeatedly prescribed medication without first performing any significant examination or evaluation, based on what the patient requested, so frequently that experts testified it would not have

occurred in the usual course of professional practice. They involve defendants who repeatedly dispensed medications to known addicts and at such prices that experts testified the prescriptions could not have been for legitimate medical purposes. Assuming the evidence presented at trial in this case is similar, the court agrees with the government that there is no reason or rationale for instructing a criminal jury about malpractice. While the notion of "usual course of practice" brings to a lawyer's mind the similar concept of "standard of care," a phrase common in malpractice cases, the court suspects that non-lawyer jurors are less likely to think that way, particularly if they are instructed at the beginning and the end of the trial that the government must prove all the elements of the offense beyond a reasonable doubt.

At this point, the court does not plan to give Lisa Hofschulz's proposed instruction titled "Not Malpractice." Dkt. No. 115 at 39. If, however, witnesses or parties use language at trial that implies or states that the jury may find the defendants guilty if they were negligent, the court will reconsider this ruling.

D. Conclusion

The court **PRELIMINARILY ORDERS** that it will give the instructions proposed by the government, and not the instructions proposed by Robert Hofschulz and Lisa Hofschulz. Dkt. No. 115 at 20-39.

The court **ORDERS** that this ruling is subject to review and revision if the evidence at trial requires it.

Dated in Milwaukee, Wisconsin this 12th day of July, 2021.

BY THE COURT:

HON. PAMELA PEPPER
Chief United States District Judge